TECHETHOS

FUTURE ○ TECHNOLOGY ○ ETHICS

Annex 9.4 National Legal Case Study: Neurotechnologies in Germany

D4.2 Comparative analysis of national legal case studies

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D4.2 National legal case studies: Annex 9.4 - Neurotechnologies in Germany			
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Lead Partner	Trilateral Research (TRI)		
Lead Author(s)	Lisa Häberlein (EUREC)		
Other contributors	Julie Vinders, Ben Howkins (TRI)		
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The TechEthos Project

TechEthos is an EU-funded project that deals with the ethics of the new and emerging technologies anticipated to have high socio-economic impact. The project involves ten scientific partners and six science engagement organisations and runs from January 2021 to the end of 2023.

TechEthos aims to facilitate “ethics by design”, namely, to bring ethical and societal values into the design and development of new and emerging technologies from the very beginning of the process. The project will produce operational ethics guidelines for three technologies for users such as researchers, research ethics committees and policy makers. To reconcile the needs of research and innovation and the concerns of society, the project will explore the awareness, acceptance and aspirations of academia, industry and the general public alike and reflect them in the guidelines.

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Term	Explanation
Neurotechnology	Devices and procedures used to access, monitor, investigate, manipulate, and/or emulate the structure and function of the neural systems of natural persons.[1]

Table 2: List of Abbreviations

Term	Explanation
ABFTA	Ausschuss für Bildung, Forschung und Technikfolgenabschätzung
AGG	Allgemeines Gleichbehandlungsgesetz
AI	Artificial Intelligence
BCI	Brain Computer Interface
BDSG	Bundesdatenschutzgesetz
BGB	Bürgerliches Gesetzbuch
BGH	Bundesgerichtshof
BMBF	Bundesministerium für Bildung und Forschung
BVerfG	Bundesverfassungsgericht

[1] OECD. (2019) *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457.

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CHRB	Convention on Human Rights and Biomedicine
DBS	Deep brain stimulation
DFG	Deutsche Forschungsgemeinschaft
DS-GVO	Datenschutz-Grundverordnung
fMRI	Functional magnetic resonance imaging
MPG	Gesetz über Medizinprodukte
NKR	Nationaler Normenkontrollrat
StGB	Strafgesetzbuch
TAB	Büro zur Technikfolgenabschätzung
THS	Tiefe Hirnstimulation
Vzbv	Verbraucherzentrale Bundesverband
XR	Digital extended reality

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Abstract

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in Germany, as evidenced in policy, legislation (including, where applicable, proposals to create new law or adapt existing law in response to neurotechnological developments), case law and regulation. It focuses on those issues affecting and/or contributing to fundamental human rights and freedoms, socio-economic inequalities, and stimulation of innovation within the domains of human rights law, privacy and data protection law, the use of neurotechnologies in criminal and civil legal proceedings, and liability for harms under tort, contract and criminal law. This sets out the extent to which these legal domains already regulate neurotechnologies, before highlighting the ongoing gaps and challenges in the existing legal frameworks.

A summary overview of the main findings and legal issues surrounding neurotechnologies in Germany is provided in Section 4.1.1 of the TechEthos Deliverable 4.2 summary comparative overview, to which this individual national legal case study report is annexed. In conjunction with the other national legal case studies on neurotechnologies and the other two technology families, namely climate engineering and digital extended reality (XR) technologies, this report provides the basis for the various neurotechnology-specific and cross-cutting regulatory challenges outlined in the summary comparative overview. This report is primarily aimed at informing relevant stakeholders, including German policymakers and regulators, of the main regulatory gaps and challenges applicable to neurotechnologies in Germany.

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1. Introduction

Neurotechnologies present many significant legal issues that impact socio-economic equality and fundamental rights in Germany. This study provides an overview of those legal issues and challenges.

This study analyses relevant laws and policies from the German legal system in relation to neurotechnologies. There is no comprehensive or dedicated legislation in Germany governing this technology family, but many elements of existing laws and policies would apply to the use of such technologies. For the purpose of the TechEthos project and this national legal case study, we have used the following definition for neurotechnologies:

> **Neurotechnologies** refers to devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons.[2]

The definition for this technology family is based on the TechEthos factsheets, as developed by work package 1 team members as part of the initial horizon scan.[3] For more information about the TechEthos technology families and their innovation ecosystems, visit: https://www.techethos.eu/resources/.

1.1 Purpose of the German national legal case study

The objective of this study is to review the current state of the law on and legal responses to neurotechnologies in Germany, as evidenced in policy, legislation, case law and regulation. Since there is no specific neurolaw in Germany, this study highlights and explore those which laws could be specifically relevant to neurotechnological applications in Germany. For this purpose, current debates and future policy and legal developments are referred to. In addition, proposals for special neurotechnology laws and existing laws that are or could be relevant for emerging neurotechnologies in the future are mentioned. Exemplary domain-specific legal issues are described to reflect the breadth and depth of legal dimensions. These are primarily problem areas that may challenge the German legal system and mostly remain unanswered at present, e.g., questions about neurorights being discussed as a complement to existing law, neuroimaging, brain computer interfacing techniques, or deep brain stimulation. Consideration is given to human rights dimensions as well as to legislation at the European and German national levels, considering public law (academic freedom), civil law (data protection and informed consent) and criminal law (end of life decisions).

In addition to the reasons mentioned above, the selection of Germany as a national legal case study is intended to complement the other national legal case studies on neurotechnologies, specifically, and the other technology families, more generally. For the purposes of this deliverable, at least one common

[2] OECD. (2019) *Recommendation of the Council on Responsible Innovation in Neurotechnology*, OECD/LEGAL/0457.
[3] TechEthos (2022) *Technology Factsheet: Climate Engineering / TechEthos,* [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Climate-Engineering_website.pdf; TechEthos (2022) *Technology Factsheet: Neurotechnologies / TechEthos,* [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Neurotechnologies_website.pdf; TechEthos (2022) *Technology Factsheet: Digital Extended Reality / TechEthos,* [Online]. Available at: https://www.techethos.eu/wp-content/uploads/2022/05/TechEthos_factsheet_Digital-Extended-Reality_website.pdf.

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law jurisdiction and at least one civil law jurisdiction was selected for each of the three technologies families, to ensure a full range of legal frameworks would inform the comparative analysis. As an extensive study of EU law (and international law) in relation to the three technology families has been conducted for Deliverable 4.1, it was decided that it would be beneficial to represent both EU and non-EU jurisdictions in the national legal case studies, in order to explore both how EU law is operationalised at a national level, as well as how non-EU frameworks differ from the approaches of EU Member States.

This study was prepared through desk research, using legal academic literature and legislation tracker databases, such as…It is part of a series of national legal case studies prepared in the TechEthos project covering three technology families, namely: climate engineering, neurotechnologies, and digital extended reality (XR). A complementary report covers the international and European Union law dimensions of the three technology families (D4.1 of the TechEthos project).[4] The following table provides an overview of the nine country studies conducted as part of the *Comparative analysis of national legal case studies* (D4.2 of the TechEthos project):

Table 3: Overview of nine national legal case studies (TechEthos WP4)

Climate Engineering	Neurotechnologies	Digital Extended Reality
Australia	Germany	France
Austria	Ireland	Italy
United Kingdom	United States	United Kingdom

1.2 Structure of the case study

Section II explores the existing and proposed laws and policies in Germany that specifically address neurotechnologies. **Section III** explores the legal implications of neurotechnologies in relation to selected legal domains. **Section IV** provides an overview of the gaps and challenges in relation to the regulation of neurotechnologies. **Section V** concludes the case study, followed by a reference list at the end.

1.3 Scope and Limitations

This national legal case study was prepared as part of TechEthos Work Package 4 on policy, legal and regulatory analysis of the three identified families of technologies, namely climate engineering technologies, neurotechnologies and digital extended reality (XR) technologies. The following results are based on desk research and do not represent a comprehensive analysis of all possible legal issues pertaining to neurotechnologies. Rather, this study focuses on a set of pre-defined issues which are likely to have a high socio-economic impact. As the legal situation regarding the use of neurotechnologies in Germany is still in its early stages, international academic publications as well as the voices of researchers from German-speaking countries and the current public discourse were considered with the attempt to relate ongoing debates to existing law and to describe possible scenarios. The domain-specific legal issues described herein therefore have an exemplary character.

[4] Santiago, N., et al. (2022). TechEthos D4.1: *Analysis of international and EU law and policy.* TechEthos Project Deliverable. Available at: www.techethos.eu.

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1.4 Overview of the German legal system

The legal system in Germany is divided into civil law and public law, whereby civil law regulates the legal relations of individual citizens to each other and has as its core in the **German Civil Code** (in German "Bürgerliches Gesetzbuch", BGB), which contains regulations for everyday life, for example for guardianship.[5] In contrast, public law regulates the relationship of the individual to the public authority and the relationship of the public powers to each other. Public law includes, for example, criminal and procedural law as well as constitutional law and international law. The law system is founded on the principles laid out by the **Basic Law** (in German "Grundgesetz"), the constitution of the Federal Republic of Germany.[6] The articles of the Basic Law stand above all other German legal norms and determine the fundamental state system and value decisions. It is made up of the national, **federal government** (in German "Bund") and the 16 **regional states** (in German "Länder"). The powers and functions of the federal government and the regional states are strongly separated.[7] For further information on the German legal system see the report developed by the SATORI project.[8] Both have their own executive, legislative and judiciary branches with several instances within each of the five independent branches of court, which are distinguished by the terms **"ordinary jurisdiction"** (in German "ordentliche Gerichtsbarkeit") and **"special jurisdiction"** (in German "besondere Gerichtsbarkeit"). The ordinary jurisdiction comprises the civil and criminal courts, while the special jurisdiction includes administrative courts, labour courts, social courts and finance courts.[9]

Federal legislative power

Federal legislative power is divided between the **German parliament** (in German "Bundestag"), which is directly elected by the German citizens and the **German federal council** (in German "Bundesrat") which represents the governments of the 16 regional states. Thus, in Germany's federal system, the regional states hold a considerable share of the powers of the state and are also involved in the legislative process. Generally, the parliament has more influence than the federal council and is the most important body pertaining to the adoption of a new law or the amendment of existing law. However, the agreement of the federal council in the legislative process is often required, since federal legislation frequently has to be executed by state or local agencies. The deputies and parliamentary groups of the parliament can introduce new legal proposals or amendments as drafts.[10] Here the debate, consultation and vote on the bill takes place after a fixed procedure. The federal council gets all the laws to vote and can even reject a draft depending on the nature of the law. The **Mediation Committee** is a body that acts between the parliament and the federal council. If the consent of the parliament is required for a law, the parliament and the federal government may also request the convening of the Mediation Committee to reach an agreement.[11] The **Federal Court of Justice** (in

[5] Bürgerliches Gesetzbuch (BGB) (German Civil Code) (1900). Available at: https://www.buergerliches-gesetzbuch.info/ (Accessed: 04 November 2022).
[6] Grundgesetz für die Bundesrepublik Deutschland (Basic Law for the Federal Republic of Germany) (1949). Available at: https://www.bundestag.de/gg (Accessed: 04 November 2022).
[7] Deutscher Bundestag (German Parliament) (n.d.) *Der Bundesrat (German Federal Council)*. Available at: https://www.bundestag.de/parlament/grundgesetz/gg-serie-05-bundesrat-634568 (Accessed: 04 November 2022).
[8] Nagel, S. K., Nagenborg, M., Reijers, W., Benčin, R., Strle, G., Nedoh, B. (2015) *Ethics Assessment in Different Countries. Germany. (D1.1 of the project SATORI)*. Available at: http://satoriproject.eu/media/4.e-Country-report-Germany.pdf (Accessed: 04 November 2022).
[9] Pötzsch, H. (2009) *Die Deutsche Demokratie (The German Democracy)*. 5th edn. Bonn: Bundeszentrale für politische Bildung (Federal Agency for Civic Education).
[10] In the context of this study, no existing or proposed laws explicitly addressing the topic could be found in the field of neurotechnology by means of a keyword search.
[11] Deutscher Bundestag (German parliament) *Mediation Committee*. Available at: https://www.bundestag.de/en/committees/mediation (Accessed: 04. November 2022).

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German "Bundesgerichtshof", BGH) is the supreme court of the federal republic of Germany[12]. The **Federal Constitutional Court** (in German "Bundesverfassungsgericht", BVerfG), represents both an independent constitutional body of the justice system ranking alongside the other supreme federal bodies and the supreme court at federal level[13].

Associated bodies

However, there are other bodies supporting the legislative sector, such as councils, commissions and organisations that could play an important role, especially in the future development of neurotechnologies. For example, there is scientific policy advice for the German Bundestag by the Office of Technology Assessment at the German Bundestag (in German "Büro zur Technikfolgenabschätzung", TAB)[14]. One of its main tasks is to analyse the potentials and effects of scientific and technological developments comprehensively and in a forward-looking manner and to explore the associated social, economic, ecological opportunities and risks. On this basis, action requirements and possibilities are pointed out to the committees and members of the Bundestag. The **Committee on Education, Research and Technology Assessment** (in German "Ausschuss für Bildung, Forschung und Technikfolgenabschätzung", ABFTA) forms a permanent rapporteur group each legislative period with one member from each parliamentary party in the Bundestag[15]. The **National Regulatory Control Council** (in German "Nationaler Normenkontrollrat") advises the German federal government as an independent body to ensure the necessary level of transparency on the compliance costs of legislation for decision makers in government and parliament as to make clear which cost and time requirements may arise from laws, ordinances and administrative regulations for citizens, businesses and public authorities[16]. The **German Ethics Council (**in German "Deutscher Ethikrat") on the other hand, is an independent council of experts that monitors the ethical, societal, scientific, medical and legal issues as well as potential consequences, particularly in the field of the life sciences and their application to human beings. The **Data Ethics Commission** (in German "Datenethikkommission") is an independent advisory body in the field of digital policy established by the German Federal Government in 2018[17]. To name just one more relevant body, organisations like the **Federation of German Consumer Organisations** (in German "Verbraucherzentrale Bundesverband", vzbv) are associations organised at state level, dedicated to consumer protection on the basis of a state mandate and to provide advisory services on, for example, AI applications, data protection and product safety[18]. The following text refers to some of these structures to show where neurotechnologies are or could be considered in the German legal system.

[12] The Federal Court of Justice. Available at: https://www.bundesgerichtshof.de/EN/Home/homeBGH_node.html;jsessionid=468D92B51CDC9037A945CF23ACAD1AEB.1_cid359 (Accessed: 04 November 2022).
[13] The Federal Constitutional Court. Available at: https://www.bundesverfassungsgericht.de/EN/Homepage/home_node.html (Accessed: 04 November 2022).
[14] Büro zur Technikfolgenabschätzung (Office of Technology Assessment at the German Bundestag). Available at: https://www.tab-beim-bundestag.de/english/ (Accessed: 24 October 2022).
[15] Ausschuss für Bildung, Forschung und Technikfolgenabschätzung (Committee on Education, Research and Technology Assessment). Available at: https://www.bundestag.de/bildung (Accessed: 04 November 2022).
[16] Nationaler Normenkontrollrat (National Regulatory Control Council). Available at: https://www.normenkontrollrat.bund.de/nkr-en (Accessed: 04 November 2022).
[17] Datenethikommission (Data Ethics Commission). Available at: https://www.bmi.bund.de/DE/themen/it-und-digitalpolitik/datenethikkommission/datenethikkommission-node.html (Accessed: 04 November 2022).
[18] Verbraucherzentrale Bundesverband (vzbv)) (The Federation of German Consumer Organisations). Available at: https://www.vzbv.de/en (Accessed: 04 November 2022).

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Criticism of the jurisdiction

The legal system enjoys a high reputation in Germany. Nevertheless, there is much criticism of the jurisdiction, most of which is not directed against the judicial organs but against shortcomings for which the legislator is responsible. Criticism is directed at the fact that there are too many laws, which are becoming a flood of standards, that the laws are too complicated and abstract for laypersons, that court proceedings take too long, cause enormous costs and then possibly end without a judgement, or that courts are interfering more and more so that political conflicts become legal disputes.[19]

1.5 Current state of neurotechnologies in Germany

The National Regulatory Control Council (in German "Nationaler Normenkontrollrat", NKR) recently called for reform of the legislative process in Germany. Chairman of the NKR, Lutz Göbel, stated that laws are often passed overly fast and under time pressure, leading to errors and undesirable consequences, as well as a lot of bureaucracy. He suggested involving more experts in the process in advance[20]. This demand also allows conclusions to be drawn about the development of neurotechnologies and their legal implications, as far as better knowledge of the brain could lead to better-designed laws and fairer legal procedures. Researchers like Eckhardt et al. call for legislators to keep a close eye on the situation to ensure the safety and efficacy of neurotechnological products. They describe that the current relatively widespread assignment of nonmedical bioelectronic products to medical products, with their more burdensome testing procedures, hinders technological progress and increases the cost of these products.[21]

Terms like "neuroethics", "neuroright", "neurocrime", and "neurosecurity" (in German "Neuroethik", "Neurorecht", "Neurokrimininalität" and "Neurosicherheit") are part of the academic discourse, yet they are not actually recognised in the public discourse. The discipline of "neuro-criminology" (in German "Neurokriminologie"), which deals with the origin of criminal offences and, with increasing urgency, also addresses the question of effective measures of rehabilitation and prevention, is just emerging[22].

Hence, there are only limited neurotechnology-specific policy and legal developments in Germany. National debates, that affect neurotechnology either directly, for example, in the academic discourse, or indirectly, for example, in the political debate on the reform of the legal system, tend to be oriented towards the international, especially Anglo-American, discourse. In this respect, however, there are considerations as to whether and to what extent neurotechnologies might influence relevant national laws, such as German criminal law.

Currently, neurotechnology is an internationally dynamic field of research with intensive research activities also existing in Germany. Research institutions, like Fraunhofer and Max-Planck play an

[19] Pötzsch, H. (2009) *Die Deutsche Demokratie (The German Democracy)*. 5th edn. Bonn: Bundeszentrale für politische Bildung (Federal Agency for Civic Education).
[20] Nationaler Normenkontrollrat (National Regulatory Control Council) (2022) *Welcome to the NKR website*. Available at: https://www.normenkontrollrat.bund.de/nkr-en (Accessed: 04 November 2022).
[21] Eckhardt, A., Abegg, A., Seferovic, G., Ibric, S., Wolf, J. (2022) *Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik (When people network their bodies with technology. Fundamentals and perspectives of non-medical bioelectronics)*. Bern: ETH Zürich, p. 22. Available at: https://www.research-collection.ethz.ch/bitstream/handle/20.500.11850/565525/1/9783728141385.pdf (Accessed: 04 November 2022).
[22] Duttge, G. (2015) 'Einsatz von Neurotechnologie: Zukunftsperspektiven eines modernen Sanktionensystems?', in Kathrin Höffler (ed.). Brauchen wir eine Reform der freiheitsentziehenden Sanktionen? Göttinger Studien zu den Kriminalwissenschaften. Universitätsverlag Göttingen. 27eth edn. p. 116.

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important role in this area, although no research results could be found in the context of this study on keywords such as “neuroright”, and the like[23]. The same applies to funding programmes like the one already launched in 2004 by the Federal Ministry of Education and Research (in German “Bundesministerium für Bildung und Forschung”, BMBF) to establish the basic structural framework in the field of computational neuroscience in Germany.[24] It can be assumed that legal issues related to neurotechnologies will play an important part in projects like the before mentioned or, for example, in those of the German Research Foundation (in German “Deutsche Forschungsgemeinschaft”, DFG), responsible for the promotion of science and research in the Federal Republic of Germany, which deals with the topic as well, for example by means of publications, but also by initiating conferences or by funding initiatives.[25]

[23] Eckhardt, A., Abegg, A., Seferovic, G., Ibric, S., Wolf, J. (2022): ‘Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik‘. Bern, Switzerland: TA-SWISS 78. p. 187. Available at: https://doi.org/10.3218/4138-5 (Accessed: 24 October 2022).
[24] With the funding programme "National Bernstein Network Computational Neuroscience" (NNCN), the BMBF aims at supporting structures that bundle, strengthen and network the outstanding expertise available in Germany in the experimental and theoretical neurosciences. Available at: https://www.bmbf.de/bmbf/de/forschung/gesundheit/lebenswissenschaftliche-grundlagenforschung/nationales-bernstein-netzwerk-computational-neuroscience.html (Accessed 04. November 2022).
[25] Deutsche Forschungsgemeinschaft (DFG) (German Research Foundation). Available at: https://www.dfg.de/en/dfg_profile/what_is_the_dfg/index.html (Accessed: 04 November 2022).

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2. Neurotechnology-specific legal and policy developments

This section presents an overview of the legal and policy developments pertaining to neurotechnologies in Germany. It examines relevant policies and laws in relation to neurotechnologies and identifies the national authorities involved in the implementation and enforcement of such laws and policies.

Current debates and future policy and legal developments

Discussions around the topic of neurotechnologies and its legal implications were limited in scope and showed signs of fatigue even before not too many years ago. The German Philosopher and Psychologist Stephan Schleim argued in 2012 that "evidence for an impending normative '**neuro-revolution'** is scarce and neuroscience may instead **gradually improve legal practice** in the long run, particularly where normative questions directly pertain to brain-related questions".[26] It is only recently that practical and normative questions of neuroscience have come into focus of law, for which there is now a **multifaceted discussion** - not only about the possible impact of neuroscience on **criminal law,** but also with regard to the level of **civil law**.[27] Considering that neurotechnological devices can influence sensory perception and cognitive as well as emotional states, reflections focus on the connection between freedom of the will and culpability.[28] For example, there is the concern that neurotechnologies may challenge existing notions of **free will and culpability** and threaten established social practices of punishment. For example, brain stimulation or surgery as an alternative to punishment has been discussed in criminal law contexts since brain stimulation research of the 1950s to 1970s. Culpability changed by neuroscience will demand corresponding **modifications of legal standards to improve current practices**.[29]However, Germany seems behind the international trend towards diversification of types of punishment. The current criminal law system and criminal procedure applicable to adults in Germany, especially in contrast to youth criminal law, which provides a differentiated spectrum of intervention options depending on the need for rehabilitation according to individual maturity development and socialisation, is considered to be in urgent need of revision, insofar as the options for punishment are limited to the alternative of a financial penalty or imprisonment.[30] Already in 2000, the Commission

[26] Schleim, S. (2012) 'Brains in context in the neurolaw debate: The examples of free will and "dangerous" brains', *International Journal of Law and Psychiatry*, 35(2), p. 104-111. Available at: https://doi.org/10.1016/j.ijlp.2012.01.001 (Accessed: 24 October 2022).
[27] Spranger, T. M. (2015) ‚Prolegomena zu den praktischen Herausforderungen der Neurowissenschaften (Prolegomena to the practical challenges of neuroscience)', Jahrbuch für Wissenschaft und Ethik, 19th edn.(1), pp. 61-64.
[28] Duttge, G. (2015) 'Einsatz von Neurotechnologie: Zukunftsperspektiven eines modernen Sanktionensystems?', in Kathrin Höffler (ed.). Brauchen wir eine Reform der freiheitsentziehenden Sanktionen? Göttinger Studien zu den Kriminalwissenschaften. Universitätsverlag Göttingen. 27eth edn. p. 111.
[29] Schleim, S. (2012) 'Brains in context in the neurolaw debate: The examples of free will and "dangerous" brains', *International Journal of Law and Psychiatry*, 35(2), p. 104-111. Available at: https://doi.org/10.1016/j.ijlp.2012.01.001 (Accessed: 24 October 2022).
[30] Duttge, G. (2015) 'Einsatz von Neurotechnologie: Zukunftsperspektiven eines modernen Sanktionensystems?', in Kathrin Höffler (ed.). Brauchen wir eine Reform der freiheitsentziehenden Sanktionen? Göttinger Studien zu den Kriminalwissenschaften. Universitätsverlag Göttingen. 27th edn. p. 111.

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called for a reform of the criminal penalty system to finally meet the requirements of the transformed social, technical and criminal policy framework.[31]

With regard to the emerging special discipline of neurocriminology, the possibility of developing effective measures for crime prevention and rehabilitation is discussed and explored.[32]

As far as autonomous people can determine and act in accordance with their own will, their autonomy might be affected as soon as third parties intervene in the process of will determination and capacity to act, without the informed consent of the affected person. "This could be the case, for example, if a stimulating headset – automatically controlled by means of Artificial Intelligence (AI) – changes people's moods to such an extent that, although they may comfortably perceive themselves as stronger and more self-assured, at the same time through their aggressive and insensitive behaviour they destroy valued social relationships"[33] (In the future, particularly neuroelectronic applications could raise the question of which will is to be taken into account in the execution of laws. Questions concerning neurotechnologies and self-determination might therefore affect all areas of law in which there is a connection with people's capacity for decision-making and action. However, these considerations are not without addressing the problem that German criminal law bases the central concept of culpability on a "merely fictional, logically contradictory and empirically indefensible concept of freedom of will",[34] inasmuch as it is assumed "(...) that human beings are capable of free, responsible, moral self-determination and are therefore able to decide for what is right and against what is wrong (...)"[35]. Since any resultant alternation cannot be empirically proven, this means that it also cannot be proven that a person could have acted differently, i.e. that there would have been at least two alternative options for action at a given time, the concept of culpability is replaced by the civil law concept of responsibility, which demands existing norms to be recognised as such and incorporated into one' s behaviour.

It is worth mentioning that the scientific discourse that relates to **German criminal law (StGB)** and the neurosciences is oriented toward the international, especially the Anglo-American discussion. These discussions illustrate that **neuroethics, neurolaw, neurorights and neurosecurity** are **interdisciplinary fields**.[36] This aspect is also being recognised by the Deutsche Forschungsgemeinschaft (DFG), central self-governing research funding organisation in Germany. Legal experts, psychiatrists and ethicists are discussing the **challenges that neuroscience poses to the legal system**. Knowing the neuroscience is an area that is generally well suited to international cooperation, the research funding organisation enabled researchers to learn about research and cooperation opportunities in Germany at the international congress on "Brain, Behaviour and Emotions" in 2019.[37]

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[31] Ibid. p. 112.
[32] Ibid. p. 216f.
[33] Eckhardt A., Abegg A., Seferovic G., Ibric S., Wolf J. (2022) *Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik (When people network their bodies with technology. Fundamentals and perspectives of non-medical bioelectronics).* Bern: ETH Zürich, p. 187. Available at: https://www.research-collection.ethz.ch/bitstream/handle/20.500.11850/565525/1/9783728141385.pdf (Accessed: 04 November 2022).
[34] Roth, G. (2015) 'Strafrechtliche Willensfreiheit und zivilrechtliche Freiheit der Willensbestimmung aus Sicht der Hirnforschung (Criminal law freedom of will and civil law freedom of will determination from the perspective of brain research), *Jahrbuch für Wissenschaft und Ethik*, 19eth edn. (1), p. 65-76.
[35] Ibid, citing BGHSt 2, 194, 200. The decisions of the federal court (Bundesgerichtshof) in criminal matters are a collection edited by the members of the federal court.
[36] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022).
[37] DFG (2019) *Fachtagung unterstreicht Kooperationspotenzial in den Neurowissenschaften (Symposium highlights potential for cooperation in neuroscience)*. Available at:

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Proposals for dedicated law

By making the discourse more international and interdisciplinary, also international rights such as human rights become a focus of attention. This raises the question of whether existing **human rights** legislation is adequate to protect mental privacy or whether new rights need to be created.[38] According to many lawyers and other experts, human rights relevant for neurotechnological devices, are not adequately protected by existing laws. This situation has been already addressed by **Chile**, which in 2021 drafted a constitution **to protect brain data and prohibit their use without informed consent** which however was rejected by the public in a referendum.[39] Four main neurorights have been identified to facilitate the discussion of ethical, legal and social questions that neurotechnology raises.[40] Now, the debate is about whether these rights are to be understood in absolute terms, so that no restriction would be justified, or whether they are to be understood in relative terms, so that the consent of the individual or the protection of the rights of others could justify their restriction Features of neurotechnology have different implications on the four identified neurorights, although, in clinical practice or everyday applications, all neuroright might be involved.[41]

1. The human right to **cognitive liberty** (also called **mental self-determination**) which includes two aspects:
   a) **access** to neurotechnologies and

   b) **protection against** their coercive and unconsented use[42]

   Cognitive liberty is considered the most fundamental neuroright, giving an individual the right and freedom to determine their own mental processes.[43]

https://www.dfg.de/dfg_profil/geschaeftsstelle/dfg_praesenz_ausland/lateinamerika/berichte/2019/190624_fachtagung/index.html (Accessed: 26 September 2022).

[38] Vidal C. (2022) Neurotechnologies under the Eye of Bioethics. eNeuro. Jun 17;9(3): ENEURO.0072-22.2022. Available at: DOI: 10.1523/ENEURO.0072-22.2022 (Accessed 04. November 2022) referring to Rainey et al. 2020, Ienca 2021 and Yuste et al. 2021.

[39] Guzmán, L. H. (2022) 'Chile: Pioneering the protection of neurorights', *The UNESCO Courier*. Available at: https://en.unesco.org/courier/2022-1/chile-pioneering-protection-neurorights (Accessed: 24 October 2022) as well as Stuenkel, O. (2022) 'Chile's Rejection of the New Constitution Is a Sign of Democratic Maturity', *Carnegie Endowment for International Peace*, 08 September. Available at: https://carnegieendowment.org/2022/09/08/chile-s-rejection-of-new-constitution-is-sign-of-democratic-maturity-pub-87879 (Accessed: 04 November 2022).

[40] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022) referring to Bubitz 2013, Ienca M., Andorno R. (2017) and Ienca, M. (2021).

[41] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022).

[42] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022). Examples of the relevance of these two aspects are given later in the section "Use of civil rights and data protection law in the German legal system" under "Advocating the needs of patients".

[43] The concept of self-determination is described in more detail throughout this study.

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Potential legal case: "People might demand access to the means to change their psychological processes in a desired way and they need to be protected from their coercive and involuntary application".[44]

2. The human right to **mental privacy** emphasising the personal and sensitive nature of brain data, similar to personal data which might give away private information someone wants to hide in their behaviour in certain contexts, such as a person's health condition, sexual preference, or political views.[45] The question arises whether the psychological meaning of the recorded signals can be derived from the brain alone or must be interpreted first. An additional level of interpretation makes today's neurotechnology seem less problematic from the perspective of neurorights to the extent that psychological assessments are only complemented by neurotechnologies, such as neuroimaging, and do not replace them.[46]
3. The human right to **mental integrity** refers to a **brain-computer interface** that could be misused to alter a person's psychological processes. Legal questions essentially depend on how central notions like **privacy** or **personal identity** are understood.
4. The human right to **psychological continuity** means people's perception of their own identity in the course of time. The neuroright to psychological continuity could be violated when neurotechnology is used to change someone's personality or personal identity. Legal questions essentially depend on how central notions like privacy or personal identity are understood.[47]

The following list is intended to provide an initial overview of the laws which are affected by or referred to in connection with the development of neurotechnologies or, at least, could be in the future. This is not a comprehensive list, but rather names those laws that were identified during desk research, particularly of academic texts in the German-speaking world.:

- German criminal code (StGB);[48]
- Medical product law (Medical Products Act, MPG);[49]
- German Basic Law (Art 3 Non-discrimination, Art. 5 academic freedom);[50]
- General equal treatment law (in German "Allgemeines Gleichbehandlungsgesetz", AGG);[51]
- Federal Data Protection Act (in German "Bundesdatenschutzgesetz", BDSG);[52]

[44] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022).
[45] The Federal Data Protection Act regulates the use of personal data in research. See: Data Protection Act (Bundesdatenschutzgesetz), 20.12.1990. English: https://www.gesetze-im-internet.de/englisch_bdsg/. (Accessed: 04. November 2022).
[46] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022).
[47] Ibid.
[48] Bundesamt für Justit (Federal Office of Justice) (2021) *Strafgesetzbuch (German Criminal Code)*. Available at: http://www.gesetze-im-internet.de/englisch_stgb/index.html (Accessed: 04 November 2022).
[49] Bundesamt für Justiz (Federal Office of Justice) (n.d.) *Gesetz über Medizinprodukte (Medical Products Act)*. Available at: https://www.gesetze-im-internet.de/mpg/ (Accessed: 04 November 2022).
[50] Bundesamt für Justiz (Federal Office of Justice) (n.d.) *Grundgesetz für die Bundesrepublik Deutschland (German basic law)*. Available at: https://www.gesetze-im-internet.de/gg/ (Accessed: 04. November 2022).
[51] Bundesamt für Justiz (Federal Office of Justice) (n.d.) *General Act on Equal Treatment*. Available at: https://www.gesetze-im-internet.de/englisch_agg/index.html (Accessed: 04.November 2022).
[52] Bundesamt für Justiz (Federal Office of Justice) (n.d.) *Federal Data Protection Act (BDSG)*. Available at: https://www.gesetze-im-internet.de/englisch_bdsg/index.html (Accessed: 04. November 2022).

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- EU fundamental rights: mental integrity,[53] non-discrimination,[54] and freedom of thought;[55]
- International human rights law (e.g., Universal Declaration of Human Rights, Art 10 right to fair trial,[56] The Convention on Human Rights and Biomedicine (CHRB) Art. 5 §2,[57] The Convention on the Rights of the Child.[58]

The next section considers the implications of neurotechnologies on these laws in greater detail. The cases discussed could often be assigned to multiple legal issues. The aim of the following exemplary analysis is to provide a broad picture of human rights, EU fundamental rights and German national law.

[53] European Union agency for Fundamental Rights (FRA) A*rticle 3 - Right to integrity of the person.* Available at: https://fra.europa.eu/en/eu-charter/article/3-right-integrity-person (Accessed: 04. November 2022).
[54] European Union Agency for Fundamental Rights (FRA) *Article 21 - Non-discrimination.* Available at: https://fra.europa.eu/en/eu-charter/article/21-non-discrimination#:~:text=1.,2 (Accessed 04. November 2022).
[55] European Agency for Fundamental Rights (FRA) *Article 10 - Freedom of thought, conscience and religion* Available at: https://fra.europa.eu/en/eu-charter/article/10-freedom-thought-conscience-and-religion (Accessed: 04. November 2022).
[56] United Nations (UN) *Universal Declaration of Human Rights.* Available at: https://www.un.org/en/about-us/universal-declaration-of-human-rights (Accessed: 04. November 2022).
[57] Council of Europe *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164).* Available at: https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164 (Accessed: 04. November 2022).
[58] United Nations International Children's Emergency Fund (UNICEF) *Convention on the Rights of the Child.* Available at: (Accessed: 04. November 2022).https://www.unicef.org/child-rights-convention/convention-text (Accessed: 04. November 2022).

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3. Domain-specific legal issues

This section examines the legal implications of neurotechnologies in the context of the German legal system.

The following sections analyses some of the ways in which neurotechnologies may be governed by German law and policy. Specific legal issues are identified in relation to the relevant legal framework(s) and then analysed in greater depth, with each discussion including specific references to existing (and proposed) law and an explanation of how the law may apply to the use of neurotechnologies.

3.1 The human right to fair trial: More evidence-based decisions in criminal justice through neuroimaging techniques

Neuroimaging has already found its way into the courtroom to prove the lack of or reduced culpability of defendants.[59] While the research findings of neuroimaging concerning the potential causes or therapies of mental illnesses are undisputed, however, possible areas of application in the forensic context still seem to be insufficiently defined, both in the German-speaking world and in the international arena. Obstacles result primarily from differences in the understanding and terminology of mental illness. In contrast to the great enthusiasm of the early years, the use of neuroimaging in the forensic context is now being questioned since superiority in terms of accuracy in comparison to other methods in criminal justice does not necessarily result. Therefore, the adequate translation between biological findings and the requirement of the legal system appears to be central in order to ultimately define the role and the scope of validity of neuroimaging procedures.[60]

Even if the technology has not yet been applied in Germany, assuming for the moment the results of this study are correct, in recent cases **neurogenetics** (in German "Neurogenetik") and neuroimaging evidence led to mitigated sentences demonstrating a tendency towards aggressive behaviour or the presence of a mental disorder.[61] In the future, functional magnetic resonance imaging (**fMRI**) could offer numerous opportunities in criminal trials. However, there are also fears that its use could **violate human rights.** The feeling is emerging that existing human rights may not be sufficient to respond to challenges to human rights principles with regard to the advancement of neurotechnologies.[62]. As

[59] More detailed information can be found, for example in Schleim, S. (2012) 'Brains in context in the neurolaw debate: The examples of free will and "dangerous" brains', *International Journal of Law and Psychiatry*. Available at: DOI: 10.1016/j.ijlp.2012.01.001 or in Komorowski, A., Kautzky, A., Vanicek, T., Lanzenberger, R. , Kasper, S. (2019) Neuroimaging in the forensic context – possibilities and limitations, Journal für Neurologie, Neurochirurgie und Psychiatrie. Available at: https://www.kup.at/kup/pdf/14354.pdf#search='hirnbildgebung.

[60] Komorowski, A., Kautzky, A., Vanicek, T., Lanzenberger, R. , Kasper, S. (2019) Neuroimaging in the forensic context – possibilities and limitations, Journal für Neurologie, Neurochirurgie und Psychiatrie. Available at: https://www.kup.at/kup/pdf/14354.pdf#search='hirnbildgebung' (Accessed: 04. November 2022).

[61] Schleim, S. (2021) 'Neurorights in History: A Contemporary Review of José M. R. Delgado's "Physical Control of the Mind" (1969) and Elliot S. Valenstein's "Brain Control" (1973)', Frontiers in Human Neuroscience. Available at: DOI: 10.3389/fnhum.2021.703308 (Accessed: 24 October 2022), referring to media reports on two cases decided in Italy in 2009 and 2011 widely discussed in the scientific community, e.g., Feresin, E. (2009) 'Lighter sentence for murderer with 'bad genes'', *Nature*. Available at: https://doi.org/10.1038/news.2009.1050 (Accessed: 04 November 2022).

[62] Ienca M., Andorno R. (2017) 'Towards new human rights in the age of neuroscience and neurotechnology', Life Sciences, Society and Policy 13(5). Available at: DOI 10.1186/s40504-017-0050-1 (Accessed: 24 October 2022).

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human rights have emerged as specific responses to recurring threats to basic human interests[63], human dignity[64] or the requirements of a good life[65], Ienca and Andorno argue that neurotechnologies have the potential to have an impact on human rights such as the human right to **mental privacy, the right to a fair trial** or the **principle against self-incrimination**[66]. The **German Ethics Council**[67] dealt with questions around the topic of applying neuroimaging (in German "Hirnbildgebung") techniques in the courtroom at its autumn meeting in 2013 where it was emphasised that the **multitude of data** obtained through neuroimaging **must first be put into context**. In that regard, Reinhard Merkel, a member of the German Ethics Council, stated that **neuroimaging could not replace traditional psychiatric reports**, but for the time being can only "cautiously" supplement them.[68] Even if the scientific community collaborates with experts from the field of psychology, neurobiology, mathematics, psychiatry, philosophy and other disciplines, neurotechnologies are still largely an untouched issue for human rights law.[69] However, given that the ongoing "neuro-revolution" might reshape some of the ethical and legal understandings, the implications raised by neurotechnologies for the inherent qualities of human beings requires a prompt and adapted response from human rights law, the authors argue. In particular, they insist that the growing sensitivity and availability of neurodevices in the coming years will require the emergence of new rights, or at least the evolution of traditional rights, to meet the challenges of neurotechnological developments.

3.2 A potential threat to the emerging right of mental integrity: Hacking of medical devices in brain-computer interfacing technology

Brain-Computer-Interfacing technologies (BCI) are technical devices that are used in patients as well as healthy people to control medical devices solely through brain activity. The associated risks are still largely unexplored. However, these technologies may be vulnerable to the emerging concept of **neurocrime** and **can affect the cognition, behaviour, self-determination, autonomy, or agency and privacy of individuals**, for example through malicious brain hacking.

Given the fact that legal questions essentially depend on how central notions like mental privacy or personal identity are understood, the question remains whether there is a need to explicitly recognise neurorights in fundamental rights law. The EU Charter of Fundamental Rights states in Article 3, the right to integrity of the person, that "[E]veryone has the right to respect for his or her physical and mental integrity". Still, it seems necessary to determine what exactly is to be protected when it comes to mental integrity, what constitutes the core of, for example, a person's identity, and with which brain areas this correlates. Neurorights might be difficult for third parties to measure objectively or

[63] Ibid, referring to Nickel 1987.
[64] Ibid, referring to Habermans 2010.
[65] Ibid, referring to Fagan 2005.
[66] Ibid.
[67] The German Ethics Council deals with the great questions of life and provides opinions and recommendations for orientation for society and politics. It was constituted on April 11, 2008, on the basis of the Ethics Council Act and succeeded the National Ethics Council established by the Federal Government in 2001. The members are appointed by the President of the German Bundestag. More information can be found here: https://www.ethikrat.org/en/?cookieLevel=not-set&cHash=4cedc8fcdda0b368d4409bb0febbe036 (Accessed: 26. September 2022).
[68] Medical community (2013) 'Neurobildgebung: Wie beeinflussen Bilder vom Gehirn unser Menschenbild?', Deutsches Ärzteblatt, 29 November [online]. Available at: https://www.aerzteblatt.de/nachrichten/56759/Neurobildgebung-Wie-beeinflussen-Bilder-vom-Gehirn-unser-Menschenbild (Accessed: 26 September 2022).
[69] Examples linking neurotechnologies and human rights issues are described later in the following section.

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empirically, as they are associated with a person's choices, their potential moral values, their experiences, and their biography, for example.[70]

As biological information carries private and sensitive data, whose access or manipulation by malicious actors can cause significant physical (including life-threatening), psychological or social harm to users of the technology, privacy and information security issues are emerging. In other words, brain-computer interfacing technologies can **threaten neuro-security**. In this context, the concept of computer crime is extended to neural devices. Instead of brain-computer interface, the term "**human-machine interface**" (in German "Mensch-Maschine-Schnittstelle") is often preferred in the German-speaking research landscape. Eckhardt et al. assume that this is an attempt not to reduce human beings exclusively to their brains. In addition, this term indicates differences regarding the underlying conception of human beings and linguistic classifications[71].

Furthermore, the concern is being expressed that **brain-computer-interfaces (BCIs) could be hacked**, as can happen with other medical devices[72]. As **regulation tends to advance much slower than technology**, and existing **security policies are often unable to accommodate the accelerating technological changes**, there is an awareness of the existing dangers, such as the **increase in criminal acts, due to gaps and inadequate legal and regulatory coverage.**[73] More and more medical devices such as cardiac pacemakers, surgical equipment and monitors are becoming connected and equipped in such a way that they can transmit important data on a patient's state of health via data links and can also be controlled remotely. Remote control, i.e., external, non-encrypted control of the administration of medication in insulin pumps, is regarded by researchers as particularly dangerous. Rios and Butts succeeded in demonstrating an attack scenario by programming a sender that transmits on a suitable frequency and identifies as a legitimate **remote control of an insulin pump**. Using a self-developed app, the researchers controlled this transmitter. Thus, vulnerabilities in the medical device system could allow attacks to hack into devices, reprogramme them or equip them with malicious software.[74]

Similarly, Halperin et al. (2008) experimentally demonstrated that hackers could wirelessly interfere with the security and privacy of, for example, an already commercialised implanted **cardiac defibrillator**. In their experiment, hackers were able to use homemade and low-cost devices to modify

[70] Eckhardt, A., Abegg, A., Seferovic, G., Ibric, S., Wolf, J. (2022): 'Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik'. Bern, Switzerland: TA-SWISS 78. Available at: https://doi.org/10.3218/4138-5 (Accessed: 24 October 2022).
[71] Ibid. p. 211.
[72] See for example Ienca M., Haselager P. (2016) 'Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity', Ethics and Information Technology 18 [online]. Available at: DOI: 10.1007/s10676-016-9398-9 (Accessed: 24 October 2022), or Ienca, M., Andorno, R. (2017) 'Towards new human rights in the age of neuroscience and neurotechnology', Life Sciences, Society and Policy. Available at: DOI: 10.1186/s40504-017-0050-1 (Accessed: 04. November 2022), as well as Schleim, S. (2012) 'Brains in context in the neurolaw debate: The examples of free will and "dangerous" brains', International Journal of Law and Psychiatry, 35(2), p. 104-111. Available at: https://doi.org/10.1016/j.ijlp.2012.01.001 (Accessed: 24 October 2022).
[73] Ienca M., Haselager P. (2016) 'Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity', Ethics and Information Technology 18 [online]. Available at: DOI: 10.1007/s10676-016-9398-9 (Accessed: 24 October 2022).
[74] Beuth, P. (2019) 'Diese App kann Menschen töten', ***Spiegel Netzwelt***, 17 July [online]. Available at: https://www.spiegel.de/netzwelt/apps/hacker-demonstrieren-schwachstelle-in-insulinpumpen-diese-app-kann-toeten-a-1277742.html (Accessed: 24 October 2022).

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a patient's therapies, switch off therapies altogether and trigger potentially deadly processes such as ventricular fibrillation.[75]

3.3 The lack of reliable findings and unresolved questions in deep brain stimulation

In neurotechnology, deep brain stimulation (DBS) (in German "Tiefe Hirnstimulation", THS) refers to a neuromodulation treatment involving implantation of a pulse generator called "brain pacemaker" that sends signals to specific parts of the brain via implanted electrodes. Deep brain stimulation falls under the regime of **medical product law**, namely the **Medical Products Act (MPG)** stating that a clinical trial of a medical device may not be started in Germany until an ethics committee and the higher federal authority have given their approval.[76] In this respect, it is still an open question, whether the use of an electrode in a new area of the brain affects the intended purpose of the medical device or whether it does not affect it. A reliable clarification of this question has not yet been provided.[77]

In 2017, the DFG addressed the topic of deep brain stimulation in the article "Tiefe Hirnstimulation. Stand der Wissenschaft und Perspektiven" and considers interventions in the brain particularly problematic from a legal and ethical perspective. This is because the human brain is regarded as the biological basis of central aspects of the self-image, such as self-awareness and moral capacity. Experiences with psychosurgery in the 20th century[78] nourished considerable fears in this respect. Even though deep brain stimulation does not raise any fundamentally new ethical and legal issues when used in approved indications and in the area of its clinical testing, analysing and answering ethical and legal questions associated with its research and clinical application is of great importance so that protective framework conditions can be created, and allow the full therapeutic potential to be realised[79]. In addition, it must be examined how the applicable legal regulation and ethical standards are applied in these matters[80].

Elliot S. Valenstein made specific recommendations for the ethical review of deep brain stimulation procedures and recommended that firstly, members of review boards "should be as independent as possible from doctors or researchers carrying out the procedure; second, alternatives should be considered and an ombudsman should be involved to represent the patient's perspective, particularly for children; third, there should be a clear rationale for the proposed procedure; and fourth, when patients are involved there should be honesty on whether they directly benefit from the procedure or are rather used for experimental purposes".[81]

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[75] Ienca, M., Haselager, P. (2016) 'Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity', Ethics and Information Technology 18, pp. 117–129 referring to Halperin et al. 2008 [online]. DOI: 10.1007/s10676-016-9398-9.
[76] Justiz (Federal Office of Justice) (2021) *Gesetz über Medizinprodukte (Medical Products Act)*. Available at: https://www.gesetze-im-internet.de/mpg/
[77] Deutsche Forschungsgemeinschaft (DFG) (2019): Guidelines for Safeguarding Good Research Practice. Code of Conduct, p. 69ff. Availabale at: https://www.dfg.de/download/pdf/foerderung/rechtliche_rahmenbedingungen/gute_wissenschaftliche_praxis/kodex_gwp_en.pdf (Accessed 04. November 2022).
[78] Ibid. p. 64, referring to Valenstein 1973 and 1986.
[79] Ibid. p. 64, referring to Clausen 2009.
[80] Ibid. p. 64 referring to Clausen 2011.
[81] Schleim 2021. Also see for example the DFG Guidelines for Safeguarding Good Research Practice. Avalibale at: https://www.dfg.de/download/pdf/foerderung/rechtliche_rahmenbedingungen/gute_wissenschaftliche_praxis/kodex_gwp_en.pdf. (Accessed: 04. November 2022).

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Since 2018, data protection law is also applicable in Germany - the General Data Protection Regulation (GDPR) (in German "Datenschutz-Grundverordnung", DS-GVO)[82] next to the Federal Data Protection Act (in German "Bundesdatenschutzgesetz", BDSG).[83] In this regard, informed consent is considered a fundamental standard of biomedical ethics, which is also anchored legally, for example in the **Genetic Diagnostics Act, § 8 and 9** (in German "Gendiagnostikgesetz") at federal level. Since there is a broad **lack of reliable findings on long-term courses, side effects and on** the impact on **quality of life**, patient information is only possible to a limited extent[84] which threatens the requirement of **properly and comprehensively informing patients** about the type of intervention, its goals, risks and possible side effects, as well as other evaluated treatment options. In the case of patients who cannot give their consent, the legal representative may decide within the **framework of custody or guardianship law**.

3.4 BCI-based communication in medical choices to ensure equal treatment and non-discrimination

Taking on another perspective, the use of neurotechnological devices may confer certain advantages on users to foster equal treatment or non-discrimination in relation to the **general equal treatment law** (in German "Allgemeines Gleichbehandlungsgesetz", AGG) and Article 3 of **German Basic Law** and the **non-discrimination law** (in German "Nichtsdiskriminierungsrecht").

One form of discrimination might be that seemingly neutral legislation or procedures can have a de facto discriminatory effect, for example in obtaining informed consent from people unable to speak and gesture. Advances in using neurotechnologies as communication tools are already being considered as potential decision-making devices that could help in ensuring patient's participation in medical choices, thus taking into account their interests, needs and wishes. Brain interfacing technologies, for example, can open up new ways of communicating for people who would otherwise be severely challenged or completely lack opportunities to communicate.[85] In the academic discourse, BCI-based informed consent procedures are viewed critically, since, for example, discussing and varying treatments as well as withdrawing from consent cannot be realised at any time, given that the application of the technology is complex.[86] However, the opportunity created by BCI, namely, to give patients a voice and thus to allow them to exercise their right to information and consent to medical interventions according to **the Convention on Human Rights and Biomedicine (CHRB)**, is highly valued.[87]Catley and Pywell for example argue that even if the patient's responses would not meet all the requirements for legally valid informed consent, acknowledging that BCI cannot replace custody or guardianship, "yes", and "no"

[82] Bundesministerium der Justiz (Federal Ministry of Justice) *Datenschutz-Grundverordnung (DS-GVO) (General Data Protection Regulation) (GDPR)* Available at: https://www.bmj.de/DE/Themen/FokusThemen/DSGVO/DSVGO_node.html (Accessed: 04. November 2022).
[83] Federal Office of Justice *Federal Data Protection Act (BDSG).* Available at: https://www.gesetze-im-internet.de/englisch_bdsg/index.html (Accessed: 04. November 2022).
[84] Deutsche Forschungsgemeinschaft (DFG) (2019): Guidelines for Safeguarding Good Research Practice. Code of Conduct, p. 73. Availabale at: https://www.dfg.de/download/pdf/foerderung/rechtliche_rahmenbedingungen/gute_wissenschaftliche_praxis/kodex_gwp_en.pdf (Accessed 04. November 2022).
[85] Spranger, T., M. (2014) 'Prolegomena zu den praktischen Herausforderungen der Neurowissenschaften', in: Sturma, D., Honnefelder, L., Fuchs, M. (eds.). Jahrbuch für Wissenschaft und Ethik, 19. De Gruyter, p. 62.
[86] Further elaboration on the difficulties of application can be found in Rödinger C. (2014) 'Obtaining informed consent through use of brain-computer interfacs? Future perspectives in medical health care', in: Sturma, D., Honnefelder, L., Fuchs, M. (eds.). Jahrbuch für Wissenschaft und Ethik, 19. De Gruyter, 107ff.
[87] Rödinger C. (2014) 'Obtaining informed consent through use of brain-computer interfacs? Future perspectives in medical health care', in: Sturma, D., Honnefelder, L., Fuchs, M. (eds.). Jahrbuch für Wissenschaft und Ethik, 19. De Gruyter, p. 107ff.

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answers could be used to identify whom the patient wished to have as a guardian[88]. The authors therewith make a strong argument that the wishes of patients expressed with the aid of BCI must be respected in the greatest possible way the law allows.

3.5 FMRI techniques in medical treatment and end-of-life decisions

The personal right includes the **right to self-determined dying** in the context of **personal autonomy**. The personal right is not explicitly mentioned in the German Basic Law but derives from Article 1 and 2 on human dignity.[89] It is to be regarded as a fundamental right, comparable to the rights of freedom. Indirectly, however, the personal right influences civil law as well as criminal law, where behaviour that particularly violates the private sphere is punishable. In 2020, the **Federal Constitutional Cour**t declared the ban on the **business-like promotion of suicide** (**Section 217 StGB)** to be unconstitutional on the grounds that severely ill or disabled people are often de facto unable to exercise the right to end their lives, meaning that they are dependent on the willingness of others to fulfil their wish to die.[90] This caused an intense debate among experts and the public. In the specific case, it is being examined whether the underlying offences of the paragraphs § 211 (murder), §§ 212 and 213 (homicide) and §216 (assisted suicide) of the StGB are fulfilled. Suicide is not a criminal offence under German law, so assisted suicide also remains unpunished. In this case, however, case law examines whether other criminal offences such as homicide or omission to assist (§ 323c StGB) are fulfilled.[91] FMRI techniques are considered to have important potential in treatment and end-of-life decisions for people who are otherwise unable to communicate, insofar as fMRI allows the patient's autonomy to be respected and ensures that medical decisions are made in their best interests.[92] Regarding the putative four neurorights, the right to access neurotechnologies as well as protection from their coercive use can be highlighted here as well as in the before mentioned case of equal treatment and non-discrimination.

3.6 Right to academic freedom

For all the risks associated with bioelectronics, the opportunities it opens should not be ignored. The focus on research and innovation has its basis in the fact that **academic freedom** is guaranteed in **Article 5 of German Basic Law**. In this regard, it is necessary to examine how the opportunities offered by neurotechnologies can be exploited and whether desired innovations can be facilitated or promoted. As with technological innovations in general, it must be decided at the discretion of the legislator, and thus also of society, which risks are considered broadly acceptable.[93]

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[88] Catley, P., Pywell, S. (2014) 'The ethical imperative of ascertaining and respecting the wishes of the minimally conscious patient facing a life-or-death decision', in: Sturma, D., Honnefelder, L., Fuchs, M. (eds.). Jahrbuch für Wissenschaft und Ethik, 19. De Gruyter, p. 79.

[89] Bundesamt für Justiz (Federal Office of Justice) (n.d.) *Grundgesetz für die Bundesrepublik Deutschland (German basic law) Art 2.* Available at: https://www.gesetze-im-internet.de/gg/art_2.html (Accessed: 04. November 2022).

[90] Bundesverfassungsgericht (BVerfG) (The Federal Constitutional Court) *Urteil des Zweiten Senats vom 26. Februar 2020 (Judgment of the Second Senate on 26 February 2020)- 2 BvR 2347/15 -, Rn. 1-343,* Available at: https://www.bundesverfassungsgericht.de/SharedDocs/Entscheidungen/DE/2020/02/rs20200226_2bvr2347715.html (Accessed: 04. November 2022).

[91] You can find more detailed information here: Deutsches Referenzzentrum für Ethik in den Biowissenschaften *Sterbehilfe (assisted suicide) - rechtliche Regelungen (legal regulations).* Avalaible at: https://www.drze.de/im-blickpunkt/sterbehilfe/rechtliche-regelungen (Accessed: 04. November 2022).

[92] Catley, P., Pywell, S. (2014) 'The ethical imperative of ascertaining and respecting the wishes of the minimally conscious patient facing a life-or-death decision', in: Sturma, D., Honnefelder, L., Fuchs, M. (eds.). Jahrbuch für Wissenschaft und Ethik, 19. De Gruyter, p. 77.

[93] Eckhardt, A., Abegg, A., Seferovic, G., Ibric, S., Wolf, J. (2022): 'Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik'. Bern, Switzerland: TA-SWISS 78. Available at: https://doi.org/10.3218/4138-5 (Accessed: 24 October 2022). p. 22ff.

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4. Overview of gaps and challenges

This section highlights the main gaps and challenges identified in the previous sections.

Medical bioelectronic devices have already been used successfully for several decades. Examples include devices for measuring the electrical activity of the heart, for stimulating the heart muscle (e.g., cardiac pacemakers) as well as those for electrical stimulation of the brain. By enabling the acquisition of new skills and characteristics, neurotechnologies create a more permeable boundary between human beings and machines. This can have a strong impact on society's conception of humanity, the status of human beings and the way people interact with each other.[94] Numerous challenges continue to exist, such as ensuring the stability of the components under special conditions, their compatibility, and the necessary energy supply and efficiency. The National Regulatory Control Council (in German "Nationaler Normenkontrollrat", NKR) recently called for reforming the legislative process in Germany. Chairman of the NKR Lutz Göbel stated that laws are often passed overly fast and under time pressure, leading to errors and undesirable consequences, as well as a lot of bureaucracy. He suggested involving more experts in the process in advance.[95] This demand also allows conclusions to be drawn about the development of neurotechnologies and their legal implications, insofar as better knowledge of the brain could lead to better-designed laws and fairer legal procedures. Scientific and engineering research in the field of non-medical and medical devices is closely interwined, also from an ethical and legal point of view.[96]Consequently, researchers like Eckhardt et al. call for legislators to keep a close eye on the situation to ensure the safety and efficacy of neurotechnological products. They describe that the current relatively widespread assignment of nonmedical bioelectronic products to medical products, with their more burdensome testing procedures, hinders technological progress and increases the cost of these products.[97]

[94] Ibid.
[95] Nationaler Normenkontrollrat (National Regulatory Control Council). Available at: https://www.normenkontrollrat.bund.de/nkr-en (Accessed: 04 November 2022).
[96] Eckhardt, A., Abegg, A., Seferovic, G., Ibric, S., Wolf, J. (2022): 'Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik'. Bern, Switzerland: TA-SWISS 78. Available at: https://doi.org/10.3218/4138-5 (Accessed: 24 October 2022). p. 20.
[97] Ibid. p. 22f.

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5. Conclusion

There are currently no significant cases in Germany that directly relate to neurotechnological applications. Also, in the German legal system, there is no explicit neuroright that could be applied to neurotechnologies. This means that the large body of legislation must be analysed regarding legal issues that are or potentially will be related to neurotechnologies. The analysis presented here is intended to serve as an example to show how wide-ranging the possible legal implications in the field of neurotechnologies can be. It is noticeable that these are often questions that do not necessarily point directly to legal issues relevant to neurotechnologies, such as the need for scientific findings to be reliable in order to serve as the basis for comprehensive patient consent.

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